



JUL 30 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Soflex Contact Lens Industries, Ltd.
c/o Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
13 Red Fox Lane
Littleton, CO 80127

Re: K033655
Trade/Device Name: Soflex Soft K (xylofilcon A) Soft (hydrophilic) Keratoconus
Contact Lens for Daily Wear and Soflex Soft K Toric (xylofilcon A) Soft (hydrophilic)
Keratoconus Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 14, 2004
Received: May 18, 2004

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, reading "A. Ralph Rosenthal". The signature is fluid and cursive, with the first name "A." and last name "Rosenthal" clearly legible.

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K033655

Device Name: Soflex Soft K (xylofilcon A) Soft (hydrophilic) Keratoconus Contact Lens for Daily Wear and the Soflex Soft K Toric (xylofilcon A) Soft (hydrophilic) Keratoconus Contact Lens for Daily Wear

Indications for Use: The Soft K (xylofilcon A) Soft (hydrophilic) Keratoconus Contact Lens for Daily Wear is indicated for daily wear for persons requiring keratoconus management and for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons that may exhibit refractive and/or corneal astigmatism, or post-refractive surgery corneal irregularity such as irregular astigmatism up to 2.00 D *that does not interfere with visual acuity*. The lens may be disinfected with a chemical or heat disinfection system.

The Soft K Toric (xylofilcon A) Soft (hydrophilic) Keratoconus Contact Lens for Daily Wear is indicated for daily wear for persons requiring keratoconus management and for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and non-aphakic persons that exhibit refractive and/or corneal astigmatism, or post-refractive surgery corneal irregularity such as irregular astigmatism. The lens may be disinfected with a chemical or heat disinfection system.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Simon Lee Cohen M.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K033655


Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)